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Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

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PGA Coordinator
Bureau of Customs and Border Protection
1300 Pennsylvania Avenue, N.W.
Room 52C
Washington, D.C. 20229

Re: Docket No. 02N-0278 – Comments On Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 -- Reopening Comment Period

The Slade Gorton & Co. – Boston, MA is pleased to submit comments to the Food and Drug Administration (FDA) on the Interim Final Rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), 69 Fed. Reg. 19763 (April 14, 2004) (Prior Notice Interim Final Rule).

Slade Gorton & Co., Boston is a major importer, distributor and exporter of a diverse line of fresh and frozen seafood as well as a processor of value-added seafood products. We have additional facilities and offices located in FT. Lauderdale, FL (2), Atlanta, GA, Chicago, IL., Los Angeles, CA and San Francisco, CA.

As a firm that relies in large measure on imported seafood we support the work of the Food and Drug Administration (FDA) and the Bureau of Customs and Border Protection (CBP) to provide food security for the entire U.S. food supply, which includes imports. Our firm wishes to cooperate in assuring that the new food security regulations, such as the submission of prior notice for imported food entries, are effectively implemented.

We are encouraged by FDA's efforts since the passage of the Bioterrorism Act to craft a workable scheme for the provision of prior notice to importation of food articles. We appreciate the agency's efforts on outreach and educational efforts concerning the new regulations. In particular, the graduated enforcement policy, which has emphasized education and information over enforcement at the outset, has aided in a smoother implementation of these new requirements.

While the graduated enforcement policy has facilitated a mostly smooth transition into compliance with prior notice requirements, the last few months have provided an opportunity for our firm and other companies that work with us on the importation process, such as customs brokers, to make observations about and identify some concerns with the prior notice system (PN).

Our firm is member of the National Fisheries Institute (NFI), a U.S.-based national seafood trade association, which is a member of the National Coalition of Food Importing Associations (NCFIA). It has come to our attention that the NFI, through the NCFIA, has submitted detailed comments in response to this Federal Register Notice concerning the interim final rule on prior notice. We wish to support the comments submitted to this docket by the NCFIA. The key comments contained in the letter submitted by NCFIA are outlined briefly below. Please refer to the NCFIA letter for a detailed discussion of each recommendation.

The specific recommendations we would like FDA to address include:

1. Creating an exemption for pre-purchase and trade samples imported for research/development purposes and laboratory and/or organoleptic analysis;

2. Resolving PN/Automated Broker Interface(ABI) system problems so that CBP entry and prior notice need not be made at the same time. Resolution of this timing problem is especially critical because for many foods, prior notice must be submitted before entry can be made (e.g., for quota class merchandise subject to CBP "live entry" requirements) and current system configurations can make it impossible to comply with both CBP and prior notice requirements.

3. Resolving PN/ABI system problems so that CBP entry can be made for articles of food that are already in the United States;[1]

4. Establish a system to communicate refusals and rejections to the importer, and to the ultimate consignee, if different, and to the electronic filer, if different, as well as the carrier;

5. Establish a system for swift resolution of technical and operational problems;

6. Establish a system that validates data and resolves conflicts between CBP and FDA databases;

7. Resolve the problem of duplicate prior notice filings;

[1] We note that with several of the timing issues cited above, the issue arises because once Customs entry is made, the filer is locked out of the system altogether. De-linking these two systems so that Customs entry is no longer so closely tied to the prior notice may ease these problems.

8. Create provision for correction of errors in prior notice submissions, so long as corrections are made prior to passage of the 2, 4 or 8-hour deadline;

9. Improve the capacity of the FDA Prior Notice Internet System Interface; and

10. Continue to improve FDA communication to, and involvement with, the importing community.

All of the previously listed recommendations address important and valid concerns observed by our firm and other food importers, however, we wish to elaborate slightly on a few of the issues. Trade samples are vital to the seafood industry because they allow U.S. firms to evaluate potential new overseas suppliers and products. These samples arrive in very small quantity and are used for internal evaluation purposes only. They are not distributed or sold for commercial purposes. An exemption from prior notice for trade samples, with the stipulations outlined in the NCFIA letter, is reasonable, workable and necessary to prevent an unnecessary hardship on the food industry.

Although seafood is generally not classified as quota class merchandise for Customs purposes, we are interested in resolution of the problem identified in item number two in list. Specifically, this issue is associated with the difference in regulatory time deadlines for prior notice versus CBP entry (i.e. the timing problem and connection between the CBP's ABI system and FDA's PN system). Seafood importers sourcing from points reachable by air in less than four hours may experience these problems due to the existing "wheels up" policy of CBP. While accounting for perhaps a minority of seafood entries, the problem creates serious challenges for effected products and the importers and brokers handling these items.

We strongly support the fourth recommendation of the NCFIA that FDA and CBP establish a system to inform importers and customs brokers when a refusal of an entry has occurred as a result of inadequate prior notice. The reasons for notifying importers and brokers, as outlined in the NCFIA letter, are compelling. We believe our firm is typical in wishing to know as soon as possible if such a refusal occurs. As consignees, owners, etc of the food, it is in our interest to quickly cooperate with the agencies to resolve inadequacies expeditiously. Carriers have considerably less interest in the matter and, in fairness to them, are not in a ready position to enact a correction or deal with the matter effectively.

Regarding communications to the trade about errors in filed prior notices, we believe the agencies must expand on their current outreach efforts. We note and appreciate that FDA recently issued and posted on its website a preliminary compliance report on prior notice. However, seafood importers attending a recent NFI Board meeting expressed a strong desire to receive timely and more detailed information about the types of errors and inadequacies the agencies are observing relative to the submission of prior notices. Moreover, individual firms like ours are eager to know whether they are in compliance and, if not, in what way they are failing. Obviously, we would like to receive this information before the later and more serious enforcement stages of the compliance policy begin.

We also strongly agree with the recommendation outlined in number eight. There appears to be no good reason not to allow the submission of revisions to the prior notice in FDA's PN system without fully canceling and re-submitting a new notice. Human errors can and do occur in the filing process and information about the entries can change. Allowing changes without having to cancel the notice would make the process much less burdensome and will help to avoid the subsequent problems associated with cancellation of the original prior notice. Food security will not be compromised by such a change in procedure provided changes to the notices occur within established timelines.

We urge FDA and CBP to create opportunities for expanded interaction with the trade. Importers and brokers are very interested in working with you to make these requirements effective for food security purposes with as little disruption to commerce as possible. Regular communication is necessary to assure this objective is met.

Furthermore, we agree with NCFIA's recommendation that after full enforcement has been in place for at least 6 months, FDA should re-open the comment period for an additional 60 days. With the benefit of a period of active FDA/CBP enforcement and surveillance, the food import community will be better able to offer informed comments to FDA on the PN System. FDA will be in a better position to evaluate the degree to which the PN System is achieving its stated goals and any problems that have arisen. FDA should issue a final rule only after this period of full enforcement and additional comment.

Lastly, we agree with NCFIA's comments on the specific questions raised in FDA's *Federal Register* notice announcing the re-opening of the comment period.

The Slade Gorton Co., Inc. wishes to thank FDA for its efforts to create a workable Prior Notice System that balances food security needs and the realities of the import trade. Your efforts on outreach are appreciated including the opportunity to submit further comments concerning the interim final rule on prior notice.

Sincerely yours,

Michael C. Gorton
CEO